MECLIZINE - meclizine hydrochloride tablet
Contract Pharmacal Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Meclizine 25 mg

Drug Facts

Active ingredient

(in each tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

for the prevention and treatment of the nausea, vomiting, dizziness associated with motion sickness

Warnings

Do not use

- In children under 12 years of age unless directed by a doctor

Ask a doctor before use if you have

- breathing problems such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- To prevent motion sickness, the first dose should be taken one hour before starting activity.
- **Adults and children 12 years of age and over:** take 1 to 2 tablets once daily, or as directed by a doctor. Do not exceed 2 tablets in 24 hours. Not for frequent or prolonged use except on the advice of a doctor.

DO NOT EXCEED RECOMMENDED DOSE

Other information

- Store at room temperature, USP

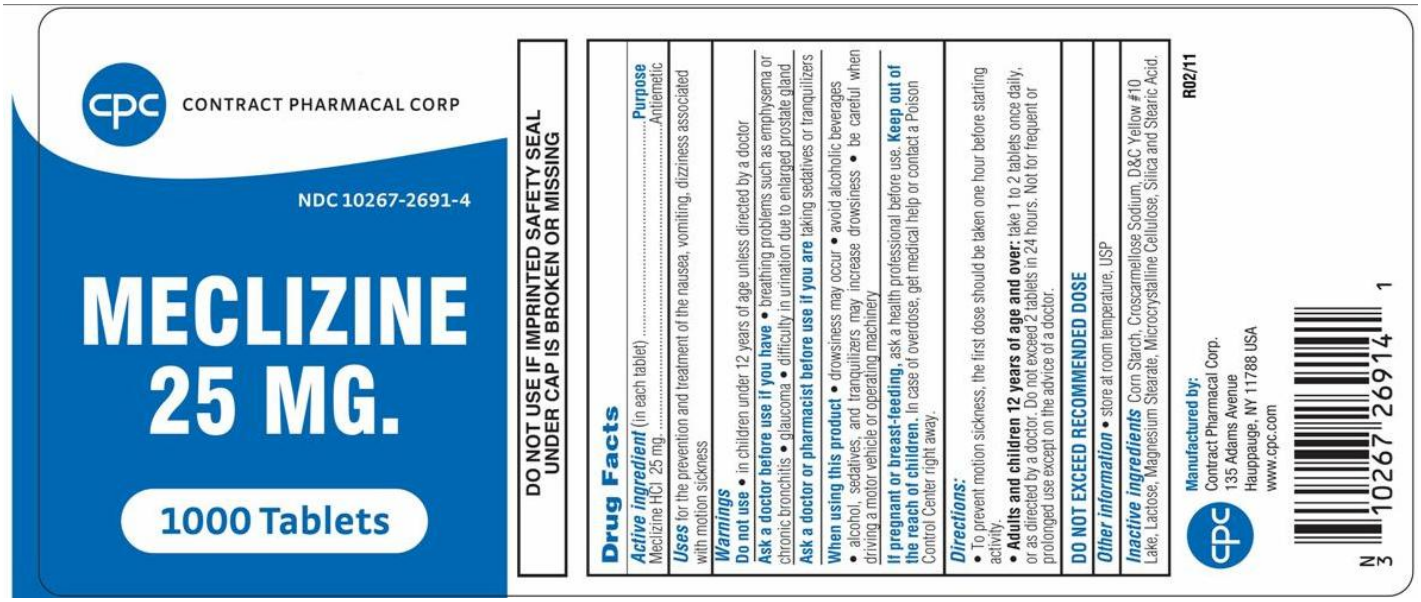
Inactive ingredient

Corn Starch, Croscarmellose Sodium, D&C Yellow #10 Lake, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Silica and Stearic Acid.

R02/11

Manufactured by:
Contract Pharmacal Corp.
135 Adams Avenue
Hauppauge, NY 11788 USA
www.cpc.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MECLIZINE

meclizine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10267-2691
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	YELLOW (Pale yellow)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	CPC;2691
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10267-2691-1	100 in 1 BOTTLE		
2	NDC:10267-2691-4	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part336	07/24/2001	

Labeler - Contract Pharmacal Corp (968334974)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		968334974	MANUFACTURE

Revised: 12/2011 Contract Pharmacal Corp